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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gary J. Calton

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2323

7590

09/10/2009

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

09/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/827,190	<b>Applicant(s)</b> CALTON ET AL.	
	<b>Examiner</b> Snigdha Maewall	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,8-17,19,20,24-32,34-37 and 39-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,8-17,19,20,24-32,34-37 and 39-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Summary*

1. Receipt of Applicants remarks, arguments and amended claims filed on 09/04/09 is acknowledged.

Claims 2, 4-7, 18, 21-23, 33, 38 and 51-54 have been cancelled.

Claims **1, 3, 8-17, 19-20, 24-32, 34-37 and 39-50** are under prosecution.

### **(Maintained Rejections)**

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 8-17, 19-20, 24-32, 34-37 and 39-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowry et al. (U.S. PG PUB 20010007878 A1) in view of Ukai *et al.*, (JP 411228450A).

Lowry et. al. teach a nutritional product in a composition comprising L-arginine for a person having renal failure. L-arginine is found to be an essential amino

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acid in patients with renal failure because of the role it plays in the synthesis of endothelium- derived relaxing factor (summary of invention). The composition can be cow-milk based, soy-based, or based on other proteins or nutrients.

Lowry et. al further suggest that the composition may also be administered via the normal oral route, and since the latter is preferred, the product's good taste is an important factor. Lowry et. al discloses that the nutritional product has moderate to high protein content and high calcium to phosphorus ratio. The composition contains vitamins, minerals and citric acid that is known in the art as flavoring agent and also water (paragraph 10, 14 and 16). The composition also typically contains emulsifiers and /or stabilizers such as carrageenan. (Paragraph 25). Lowry et al. mention that L-arginine is well known for it's unpleasant taste and has detrimental effect of bitter elemental arginine on the taste of any formulation.

Although Lowry et. al. disclose adding one or more carboxylic acids to provide good taste to the product however, it does not teach utilizing carrageenan as a taste masking agent.

Ukai *et al.* disclose a composition in which the unpleasant taste of a medicine is masked by the addition of an anionic polymer. Ukai *et al.* further disclose that the unpleasant taste such as a bitter or irritating taste, can be found among orally administered medicines, such as antibiotics, antidementials, antiallergenics and more. Ukai *et al.* further teach that the anionic polymer which masks the unpleasant taste of

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the medicine is preferably a polysaccharide, such as carrageenan, chondroitin sulfate, or dextran sulfate.

Ukai *et al.* does not specifically disclose which form of carrageenan is to be employed. However, it is the position of the examiner that this is a limitation which would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results based on the particular carrageenan employed. The results must be those that accrue from the specific limitations.

Furthermore, although the abstract of Ukai *et al.* does not disclose all of the specific types of formulations disclosed by applicant, they do disclose an oral composition. It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use this taste masking composition in any type of formulation which required taste masking. The expected results would be the same, regardless of the specific type of formulation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the taste masking composition taught by Ukai *et al.* for the masking of the bitter taste characteristically caused by L- amino acids. Ukai *et al.* teach a successful formulation, employed to mask the taste of active agents which cause a poor taste. It is unreasonable for Ukai *et al.* to list each and every active agent which may have an unsatisfactory taste. Furthermore, Lowry *et al.* teach that amino acids are well known in the art to have a characteristic bitter taste. One of ordinary skill in the art would certainly be motivated to use a composition known for success in masking poor

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taste of actives with an active known to have a poor taste. This would be clearly obvious to one skilled in the art. The expected result would be an amino acid formulation without a bitter taste. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

4. Claims 1, 3, 8-17, 19-20, 24-32, 34-37 and 39-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ukai *et al.*, (JP 411228450A) in view of Acosta *et al.* (US Patent 5,550,146).

Ukai *et al.* disclose a composition in which the unpleasant taste of a medicine is masked by the addition of an anionic polymer. Ukai *et al.* further disclose that the unpleasant taste such as a bitter or irritating taste, can be found among orally administered medicines, such as antibiotics, antidementials, antiallergenics and more. Ukai *et al.* further teach that the anionic polymer which masks the unpleasant taste of the medicine is preferably a polysaccharide, such as carrageenan, chondroitin sulfate, or dextran sulfate.

Ukai teaches oral medicine composition whose unpleasant taste is masked comprises (A) a basic medicine {for example, donepezil hydrochloride [chemical name: 1-benzyl-4-(5,6-dimethoxyindanon-2-yl)methylpiperidine hydrochloride]} having an unpleasant taste such as a bitter taste or an irritating taste among orally administered medicines such as antibiotics, antidemential medicines, antiplatelet medicines, antidepressant medicines, cerebral ameliorators and antiallergic medicines and (B) an

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anionic polymer (preferably an acidic polysaccharide such as carrageenan, chondroitin sulfate, dextran sulfate, alginic acid, gellant gum or xanthan gum). The component B is usually used in an amount of **0.1-20** pts.wt. Preferably **0.5-10** pts.wt. of the component A. (se abstract).

Ukai *et al.* does not specifically disclose which form of carrageenan is to be employed. However, it is the position of the examiner that this is a limitation which would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results based on the particular carrageenan employed. The results must be those that accrue from the specific limitations.

Furthermore, although the abstract of Ukai *et al.* does not disclose all of the specific types of formulations disclosed by applicant, they do disclose an oral composition. It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use this taste masking composition in any type of formulation which required taste masking. The expected results would be the same, regardless of the specific type of formulation.

Additionally, Ukai *et al.* do not teach that the active which causes a poor taste in the formulation is an amino acid.

Acosta *et al.* is relied upon for the teaching in column 5, lines 35-36. It states that L-amino acid mixtures have a characteristic bitter taste. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the taste masking composition taught by Ukai *et al.* for the masking of the bitter taste

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characteristically caused by L- amino acids. Ukai *et al.* teach a successful formulation, employed to mask the taste of active agents which cause a poor taste. It is unreasonable for Ukai *et al.* to list each and every active agent which may have an unsatisfactory taste. Furthermore, Acosta *et al.* teach that amino acids are well known in the art to have a characteristic bitter taste. One of ordinary skill in the art would certainly be motivated to use a composition known for success in masking poor taste of actives with an active known to have a poor taste. This would be clearly obvious to one skilled in the art. The expected result would be an amino acid formulation without a bitter taste. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### **Response to Arguments**

5. Applicant's arguments filed 09/04/09 have been fully considered but they are not persuasive.

Applicant argues that the Examiner has relied upon the Lowry et al. reference to teach a nutritional product comprising an amino acid, i.e. L-arginine, for a person having renal failure. The two references is impermissible hindsight motivation based on Applicant's own disclosure. For reasons as stated herein above, both Lowry et al or Ukai et al, taken alone or in combination, fail to render obvious Applicants' invention as now claimed. Accordingly, this rejection is improper and should now be withdrawn.

Applicant's arguments have been carefully considered but the arguments are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant's arguments that the combination of references would not have been obvious to one of ordinary skill in the art are not persuasive and the argument is not supported by any evidence. The instant claim recites the limitation of a method of inhibiting an unpleasant taste of amino acid by administering carrageenan. Lowry while teaching a nutritional composition teaches that L-arginine is well known for its unpleasant taste and has detrimental effect of bitter elemental arginine on the taste of any formulation. The formulation comprises carrageenan however does not characterize carrageenan as taste masking agent. Examiner has relied upon Ukai's reference for this specific teaching. Ukai discloses a composition in which the unpleasant taste of a medicine is masked by the addition of an anionic polymer such as carrageenan. Therefore the reference explicitly teaches its property as being taste masking agent. Since Lowry teaches that amino acids have bitter taste, one of ordinary skill would have envisaged utilizing carrageenan to the formulation of Lowry and would have come to the claimed invention.

Applicant argues that Ukai et al. fails to teach or in any way suggest an amino acid component or the use of a carrageenan (or any other masking agent for that matter) to mask the strong fishy flavor specific to an amino acid

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component. Herein again, amino acids not only possess a bitter taste but a strong fishy flavor which is difficult to mask. Consequently, Ukai et al. fails to render obvious Applicants' invention as now claimed.

Applicant's arguments are not persuasive. Instant claims recite inhibiting unpleasant taste and not fishy taste. Ukai's taste masking of bitter taste reads on the claimed unpleasant taste. Therefore the arguments In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., fishy taste) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that to cure the deficiencies of the Ukai et al. the Examiner has relied on Acosta et al. to evidence that amino acids are know in the art to have a bitter taste. Acosta discloses a nutritionally formula which uses specific free amino acids to provide the source of amino nitrogen. Acosta is silent with respect to the use of a carrageen to mask the taste of an amino acid. The Examiner has alleged that Acosta teaches that it is know in the art that amino acids have bitter taste. Applicants admit that it is known that amino acids have a bitter taste. Applicants goes further to evidence (see Sarama et al, ) that amino acids not only have a bitter taste but a characteristic foul fishy odor as well that is difficult to mask especially in large amounts generally used for medicinal purposes. Clearly, neither of the references teaches nor suggest the requisite motivation to lead one skilled in the arts to have a reasonable expectation that the

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distinct foul fishy amino acid odor can be masked by a carrageenan in the amount as claimed by Applicants.

Applicant's arguments are not persuasive. As stated earlier, claims do not define taste of amino acid to be fishy, if this criticality of the invention, it is the position of the Examiner that the limitation should be reflected in claims. Applicants allegation that Acosta does not state foul fishy taste of amino acid and Ukai does not teach inhibiting fishy taste is not persuasive in light of the scope of claims and also in light of the teachings of prior art. Acosta clearly teaches that amino acids have bitter taste and Ukai teaches masking the bitter taste which reads on the instant claims limitation of inhibiting unpleasant taste. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed.cir 1992).

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached from 8:30 Am to 5:00 PM on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on (571)-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612